PHARMA & BIOPHARMA OUTSOURCING ASSOCIATION

February 26, 2018

The Honorable Michael C. Burgess
Chairman
Subcommittee on Health
House Committee on Energy and Commerce
United States House of Representatives
2336 Rayburn House Office Building
Washington, DC 20515

The Honorable Gene Green
Ranking Member
Subcommittee on Health
House Committee on Energy and Commerce
United States House of Representatives
2470 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Burgess and Ranking Member Green,

I am writing you today on behalf of the **Pharma & Biopharma Outsourcing Association (PBOA)**, a trade association representing Contract Manufacturing Organizations and Contract Development & Manufacturing Organizations (collectively described as CDMOs for purposes of this letter). PBOA members provide the technologies and services that help the pharma and biopharma industry develop and manufacture drugs, biologics, vaccines, and other treatments safely and cost effectively. Our members represent more than 20,000 domestic manufacturing jobs, and overall manufacture more than 220 billion doses annually. CDMOs produce between 30% and 40% of all dosages consumed by patients in the U.S.

We applaud your ongoing commitment to comprehensively addressing the illicit use of opioids and combating this deadly epidemic unfolding in communities across America. With the enactment of the Comprehensive Addiction and Recovery Act in 2016, and through the Energy and Commerce Committee's ongoing consideration of additional policy proposals, you are truly leading the charge and we support your efforts.

We are, however, concerned about one of the proposals being considered at the Health Subcommittee hearing on February 28, 2018: **The Tableting and Encapsulating Machine Regulation Act of 2018**. We recognize from testimony provided to the Subcommittee by the Drug Enforcement Administration ("DEA") in 2016 that there are legitimate concerns about the illicit use of imported tablet presses and encapsulating machines, and we agree that there is an acute need to curb these practices. We also note that, in response to this activity, in late 2016 the DEA established expanded reporting requirements for all import, export, and domestic transactions involving such equipment, which were implemented in mid-2017.[1]

The legislation being considered on February 28 would reclassify **every** machine that produces either tablets or capsules in **any** domestic facility as a controlled substance, and thus subject to DEA oversight, recordkeeping, security, and other requirements – the same standards that apply to narcotic bulk drugs and finished doses. These new requirements

[1] See https://www.deadiversion.usdoj.gov/fed_regs/rules/2016/fr1230.pdf

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would be imposed without regard to whether any such machine is sited at a facility that is already regulated by the Food and Drug Administration ("FDA").

While all the implications of such a reclassification are not fully clear, this legislation, if enacted in its current form, would likely impose substantial new regulatory oversight burdens on manufacturers of both prescription and non-prescription products, most of which are not producing opioids or other controlled substances. Further, the bill would drive significant additional costs for reporting, compliance management, and security, directly reducing funds currently used to invest in growth, expand employment and drive innovation. Finally, we believe that the application of such provisions to production sites already overseen by the FDA will yield limited added enforcement value above that provided by the expanded transaction reporting requirements only recently implemented by the DEA.

We do understand and appreciate the need to more stringently oversee the acquisition and use of such production equipment that is not sited in facilities otherwise regulated by the FDA. We believe that there are several possible approaches to modify the legislation to mitigate our concerns. For example, you could specifically exclude equipment in sites regulated by the FDA under existing sections of the Food, Drug and Cosmetic, including but not limited to those relevant to producers of clinical and/or commercial supplies of prescription pharmaceuticals, over-the-counter monograph products, dietary supplements, and veterinary drugs. There are alternative approaches that we are discussing with industry trade associations and other companies, which we have agreed to review with the Committee staff in upcoming weeks.

In closing, we reiterate our support for the efforts of the Committee to address the challenges facing our country related to the illicit use of opioids. We recognize the difficult task before you, appreciate your consideration of our concerns and ideas, and restate our commitment to working constructively with you to address legitimate concerns about the illicit use of this type of the equipment without imposing inappropriate burdens on legitimate manufacturers.

Sincerely,

Gil Roth
President
Pharma & Biopharma Outsourcing Association

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PBOA Member Companies

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Afton Scientific
Alcami
Althea CMO
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Avista Pharma Services
Baxter Biopharma Solutions
Berkshire Sterile
Catalent Pharma Solutions
CMIC CMO USA
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CPC – Contract Pharmacal Corp.
DPT, a division of Mylan
Emergent BioSolutions
Grand River Aseptic Manufacturing
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